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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,713	11/27/2000	Genichiro Soma	101149-00008	7273

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT PAPER NUMBER

1645

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HA

Office Action Summary

Application No.

09/700,713

Applicant(s)

SOMA ET AL.

Examiner

Patricia A. Duffy

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16, 18, 19 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 16, 18, 19 and 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The examiner on this application has changed. Please address all future correspondence to Examiner Patricia A. Duffy, Art Unit 1645.

The response, amendments and declaration filed 11-24-04 have been entered into the record. Claims 15, 16, 18, 19 and 21-28 are pending and under examination. Claims 1-14, 17, and 20 have been cancelled.

Any objection or rejection not reiterated herein is withdrawn in view of Applicants arguments and amendments. Applicants' arguments and declaration are moot in view of the new grounds of rejection set forth below.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 16, 18, 19 and 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 15, 18, and dependent claims 19, 21, 22 and 24-28, the term "high" is a relative term that renders the claim *prima facie* indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

As to claim 24, the claim specifically indicates a concentration but the recitation of between 1 and 1000 ug is not a concentration. As such, the skilled artisan would not be readily apprised of the concentration of the feedstuff additive in the feed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly

owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soma et al (U.S. Patent No. 5,346,891 issued September 13, 1994) in view of Romanowska (Analytical Biochemistry (30(2):383-9, 1970).

Soma et al teach a low molecular weight lipopolysaccharide (LPS) purified from the genus *Pantoea* (column 8, lines 65-69) called LPS3 which is purified to 99% or higher (see column 3, lines 40-60 and columns 9-10). LPS3, having a dominant molecular weight of $6,500 \pm 2,500$ Daltons, is an effective immune stimulator as confirmed by endogenous tumor necrosis factor production (see columns 4-5). Soma et al teach that the LPS preparations may be supplied as such or in forms concentrated to any desired degree, supplied as dry powders prepared by any of the conventional means to improve stability and produced conventionally (column 4, lines 27-33). Soma et al teach that the preparations including immunity stimulators may be produced conventionally in any manner of providing medicines or veterinary medicines such as the agents may be prepared in the form of feed additives, premix preparations. The feed additives are preferably powders or granules. Any commercially available feed may be used to prepare the above-mentioned feed additives, premix preparations and such. The feed may contain minerals, vitamins amino acids and any other feed additives (see column 5, lines 49-69). Soma et al teach dose interval of 1 ug-100 mg for oral administration for a standard daily dose per day to an adult with a body weight of 60Kg and for veterinary use about one sixtieth of the above quantities may be given per 1 kg of body weight. Soma et al differ by not teaching a pure LPS3 additive that is completely free of high molecular weight lipopolysaccharide.

Romanowska teaches conventional means of purification of an LPS product based on molecular weight using sepharose gel filtration purification.

Clem et al teach that monocytes of fish perform an accessory cell function in the immune response and respond to LPS and the response of T cells and B cells is amazingly similar to the situation seen in higher vertebrates (see page 805). Clem et al teach in light of the many similarities that seemingly exist between fish and mammals in terms of the requirement for immune responses, it will not be surprising if further work in this area reveals yet more homologies (page 807, second paragraph).

It would have been *prima facie* obvious to one having skill in the art at the time that the invention was made to purify the LPS3 of Soma et al to homogeneity using any of the methods of Romanowska and add the purified LPS3 to feed as a feed additive because Soma et al teach that the LPSs of the invention may be supplied a feed or in forms concentrated to any desired degree for veterinary medicines and Clem et al teach that fish perform an accessory cell function in the immune response and respond to LPS and the response of T cells and B cells is amazingly similar to the situation seen in higher vertebrates and the pure product would be expected to have higher intrinsic activity as compared to the impure product and therefore would produce less bulk in the feedstuff.

Claims 18, 19 and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al (US Patent No 5,641,761 issued June 24, 1997) in view of Soma et al (US Patent 5,346,891 issued Sept 13, 1994) and Clem et al (Developmental and Comparative Immunology, 8(4):803-809, 1985).

Takashi et al teach that glucan shows effects for preventing infectious diseases and enhancing the immune system of fish and exhibits a similar effect in crustaceans (cols 1-2). Takashi et al teach a feed comprising a feed additive as an effective component in a concentration from 0.001 to 10% by weight (see column 5, lines 9-30). Takashi et al teach that the injected form at dose levels of 2, 5 and 10 mg/kg body weight was effective to enhance the host defense mechanisms (see columns 6-7).

Soma et al teach a low molecular weight lipopolysaccharide (LPS) purified from the genus *Pantoea* (column 8, lines 65-69) called LPS3 which is purified to 99% or higher (see column 3, lines 40-60 and columns 9-10). LPS1, having a dominant molecular weight of $6,500 \pm 2,500$ Daltons, is an effective immune stimulator as confirmed by endogenous tumor necrosis factor production (see columns 4-5). Soma et al teach that the LPS preparations may be supplied as such or in forms concentrated to any desired degree, supplied as dry powders prepared by any of the conventional means to improve stability and produced conventionally (column 4, lines 27-33). Soma et al teach that the preparations including immunity stimulators may be produced conventionally in any manner of providing medicines or veterinary medicines such as the agents may be prepared in the form of feed additives, premix preparations. The feed additives are preferably powders or granules. Any commercially available feed may be used to prepare the above-mentioned feed additives, premix preparations and such. The feed may contain minerals, vitamins amino acids and any other feed additives (see column 5, lines 49-69). Soma et al teach dose interval of 1 ug-100 mg for oral administration for a standard dose per day to an adult with a body weight of 60Kg and for veterinary use about one sixtieth of the above quantities may be given per kg of body weight.

Clem et al teach that monocytes of fish perform an accessory cell function in the immune response and respond to LPS and the response of T cells and B cells is amazingly similar to the situation seen in higher vertebrates (see page 805). Clem et al teach in light of the many similarities that seemingly exist between fish and mammals in terms of the requirement for immune responses, it will not be surprising if further work in this area reveals yet more homologies (page 807, second paragraph).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to substitute the immune stimulating low molecular weight LPS-3 from *Pantoea agglomerans* of Soma et al in the feed in the methods of activating immunity and preventing infection in fish and crustaceans according to Takashi

et al because Clem et al teach that monocytes of fish perform an accessory cell function in the immune response and respond to LPS and the response of T cells and B cells is amazingly similar to the situation seen in higher vertebrates and as such, the skilled artisan would reasonably expect that LPS-1 of Soma et al would activate immunity and prevent infection in fish and crustaceans given that Takashi another stimulating agent glucan acts similarly in both fish and crustaceans.

Status of the Claims

All claims stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

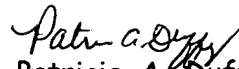
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Patricia A. Duffy, Ph.D.

Primary Examiner

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